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PATENT

Practitioner's Docket No. U 013469-7

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **Bonnie M. DAVIS**

Serial No.: 09/856,282

Group No.: 1614

Filed: June 18, 2001

Examiner: Dwayne C. Jones

For: **DOSAGE FORMULATIONS FOR ACETYLCHOLINESTERASE INHIBITORS**

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**ATTENTION: GROUP DIRECTOR**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT AFTER  
MAILING DATE OF FINAL ACTION OR NOTICE OF ALLOWANCE  
BUT BEFORE PAYMENT OF ISSUE FEE (37 C.F.R. 1.97(d))**

*NOTE: 37 C.F.R. 1.97: "(d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section [i.e., after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application], provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:*

- (1) *The statement specified in paragraph (e) of this section; and*
- (2) *The fee set forth in § 1.17(p)."*

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\***

- ☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"  
Mailing Label No. \_\_\_\_\_ (mandatory)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office. to **(571)-273-8300**

Signature

Date: October 13, 2005

**JOHN RICHARDS**

*(type or print name of person certifying)*

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** *If the information disclosure statement that contains the items required by 37 C.F.R. 1.97(d) is filed before, or simultaneously with, the payment of the issue fee, then it will be considered. See Notice of April 20, 1992 (1138 O.G. 37-41, 40) and 37 C.F.R. 1.97(d).*

### **TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

**WARNING:** *"A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.*

### **STATEMENT, PETITION AND FEE**

2. In accordance with the requirements of 37 C.F.R. 1.97(d):
  - A. Accompanying this transmittal is a statement, as specified in 37 C.F.R. 1.97(e).
  - B. Applicant hereby petitions for the consideration of the accompanying information disclosure statement. 37 C.F.R. 1.97(d)(2).
  - C. Applicant submits the petition fee set forth in § 1.17(p) (\$180.00).

**NOTE:** *"The petition should be directed to the Group Director of the examining group handling the application. The petition need do nothing more than request consideration of the information being submitted." Notice of April 20, 1992 (1138 O.G. 37-41, 40).*

### **FEE DUE**

3. Petition fee due (§ 1.17(p)): \$180.00

### **METHOD OF PAYMENT OF FEE**

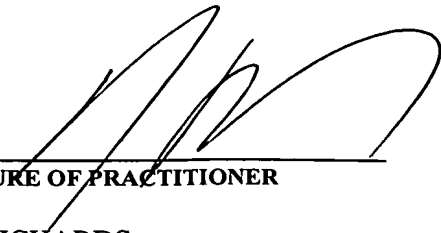
4.
  - ☒ Attached is a check for \$180.00.
  - ☐ Charge Account \_\_\_\_\_ \$180.00.A duplicate of this petition is attached.

If any additional petition fees are due, please charge Account \_\_\_\_\_.

Reg. No. 31,053

Tel. No. (212 ) 708-1915

Customer No.: 00140



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SIGNATURE OF PRACTITIONER

**JOHN RICHARDS**

*(type or print name of practitioner)*

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P.O. Address

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c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **Bonnie M. DAVIS**

Serial No.: 09/856,282

Group No. 1614

Filed: June 18, 2001

Examiner: Dwayne C. Jones

For: **DOSAGE FORMULATIONS FOR ACETYLCHOLINESTERASE INHIBITORS**

Attorney Docket No.: U 013469-7

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached references which are also listed on the attached Form PTO-1449, including AC, AD, AO and AP previously cited February 6 and June 3, 2004.

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

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**37 C.F.R. 1.8(a)**

☒ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

☐ as "Express Mail Post Office to Addressee"  
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**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office, to **(571)-273-8300**

Date: October 13, 2005

Signature  
**JOHN RICHARDS**

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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180.00 OP

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'John Richards', is written over a horizontal line.

JOHN RICHARDS  
C/O LADAS AND PARRY LLP  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NY 10023  
REG. NO. 31,053 (212) 708-1915

FORM PTO-1449

U. S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 013469-7

09/856,282

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT

Bonnie M DAVIS

FILING DATE

GROUP

JUNE 18, 2001

1614

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS	REFERENCE DESIGNATION	DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,273,260	08/2001	ColDepietro et al.	
	AB	5,643,905	07/1997	Moormann	
	AC	5,213,811	05/1993	Frisbee et al.	
	AD	4,663,318	05/1987	Davis	
	AE				
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	00/30446	06/2000	WO		
	AM	00/51970	09/2000	WO		
	AN	98/22072	05/1998	WO		
	AO	88/08708	11/1988	WO		
	AP	1,326,632	02/1994	CA		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AQ	
	AR	
	AS	

EXAMINER

DATE CONSIDERED

EXAMINER:

Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Practitioner's Docket No. U 013469-7

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **Bonnie M. DAVIS**  
Application No.: 09/856,282  
Filed: June 18, 2001  
For: **DOSAGE FORMULATIONS FOR ACETYLCHOLINESTERASE INHIBITORS**

Group No.: 1614  
Examiner: Dwayne C. Jones

**Commissioner for Patents**  
**P. O. Box 1450**  
**Alexandria, VA 22313-1450**

**STATEMENT FOR INFORMATION DISCLOSURE UNDER 37 C.F.R. SECTION 1.97(e)**

*NOTE: A statement must state either: "(1) that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. Section 1.97(e).*

*Under the first statement under § 1.97(e), it does not matter whether any individual with a duty of disclosure actually knew about any of the information cited before receiving the search report. The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. See § 609B(5), M.P. E. P., 8<sup>th</sup> Edition.*

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***  
*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- |                                     |  |  |
|-------------------------------------|--|--|
| <input checked="" type="checkbox"/> | deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. |  |
|                                     | <b>37 C.F.R. 1.8(a)</b>  | <b>37 C.F.R. 1.10*</b>   |
| <input checked="" type="checkbox"/> | with sufficient postage as first class mail.   | <input type="checkbox"/> as "Express Mail Post Office to Addressee"<br>Mailing Label No. _____ (mandatory) |

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office. to **(571)-273-8300**

Date: October 13, 2005

---

Signature  
**JOHN RICHARDS**  
*(type or print name of person certifying)*

*\* Only the date filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continue to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19. See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. If the communication contains two dates, the mailing date of the communication is the one which begins the 3-month period. The date which begins the 3-month period is not the date the communication was received by a foreign associate or the date it was received by a U.S. registered practitioner. Likewise, the statement will be considered to have been filed on the date the statement was received in the Office, or on an earlier date of mailing or transmission if accompanied by a properly executed certificate of mailing or facsimile transmission under 37 C.F.R. 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. 1.10." See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus,, for example, the certification of § 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition:

"If an information disclosure statement includes a copy of a dated communication from a foreign patent office which clearly shows that the statement is being submitted within 3 months of the date on the communication, the copy will be accepted as the required communication. It will be assumed, in the absence of evidence to the contrary, that the communication was for a counterpart foreign application.

In the alternative, a statement can be made if no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the statement after making reasonable inquiry, neither was it known to any individual having a duty to disclose more than 3 months prior to the filing of the statement."

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under Section 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information for a foreign patent office communication is not intended to represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under Section 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).



**NOTE:** *The IDS is considered filed as of the date it is received in the PTO, or on an earlier date of mailing of transmission if done so with a properly executed certificate of mailing or facsimile transmission under 37 C. F.R. § 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. § 1.10. See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.*

**NOTE:** *"The certification under Section 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.*

**NOTE:** *"The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** *"Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. Section 1.56(d) and*

*"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:*

*(1) each inventor named in the application:*

*(2) each attorney or agent who prepares or prosecutes the application; and*

*(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. Section 1.56(c).*

## **IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT FOR WHICH THIS STATEMENT IS BEING MADE**

1. This statement is being made for the Information Disclosure Statement  
☒ accompanying this statement.  
☐ filed \_\_\_\_\_  
Date

### **STATEMENT**

2. I, the person(s) signing below state:

that each item of information contained in the information disclosure statement was **first** cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

**NOTE:** *The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

### **OR**

that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

**NOTE:** "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

### IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT

3. The person making this statement is

*(check each applicable item)*

(a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

(b) ☐ a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 C.F.R. Section 1.56(c)) and who signs below.

\_\_\_\_\_  
**SIGNATURE OF PERSON MAKING STATEMENT**

\_\_\_\_\_  
*(type name of person who is signing)*

\_\_\_\_\_  
Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).
- ☒ supplied by an individual designated in Section 1.56(c).
- ☒ in the practitioner's file.

Reg. No. 31,053

Tel. No. ( 212 ) 708-1915

Customer No.: 00140

\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

**JOHN RICHARDS**

\_\_\_\_\_  
*(type or print name of practitioner)*

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023